



INFORMATION SHEET

The Vitamin D Effect on Osteoarthritis (VIDEO) Study

What is the study about?



Osteoarthritis (OA), characterized by gradual loss of cartilage, is the most common joint disorder in the world. It is one of the most frequent causes of pain, loss of function and disability in adults. OA of the knee is particularly common and currently there is no therapy that can slow the progression of OA.

Evidence suggests that vitamin D deficiency plays an important role in the development of knee OA, with low levels of vitamin D being associated with faster loss of cartilage from the knee joint. However, we do not know if correcting vitamin D deficiency using vitamin D supplements will slow this loss of cartilage and thus slow the worsening of knee osteoarthritis. VIDEO is a randomised controlled trial which will compare osteoarthritic changes in the knee in patients receiving vitamin D supplementation with those receiving a placebo.

Who is being asked to participate?



Subjects who have had symptoms of knee OA for at least 6 months and who are aged between 50 and 79 years are invited to be tested for vitamin D deficiency for this study. Those with mild to moderate vitamin D deficiency [serum 25-(OH)D levels between 12.5 and 60 nmol/l] will participate in this study.

What will the study involve?



If you agree to participate in the study we will ask you to do the following:

1. Enrol in the study now by returning your expression of interest form. Please only read your *consent form* at home; do not sign it; it will be signed in conjunction with the research officers when you come in for your first appointment.
2. Attend a screening visit where your suitability for the study will be assessed. We will take blood to test vitamin D levels, perform a knee X-ray (unless you have had a knee X-ray within the last 12 months) and ask a few simple questions about your health.

If you have mild to moderate vitamin D deficiency, we would like you to continue in the study.

If any of the following apply to you, you will not be asked to continue in the study:

- Normal vitamin D levels (>60 nmol/L). In this case, you will be given a copy of your vitamin D result.
 - Severe vitamin D deficiency (<12.5 nmol/L). In this case, we suggest that you see your GP and we will give you a copy of your results and some information to take to your GP.
 - Severe knee osteoarthritis on your X-ray, and severe or mild knee pain.
 - Having taken vitamin D supplements or an investigational drug in last 30 days.
 - Having any of the following conditions:
 - Rheumatoid arthritis, psoriatic arthritis, lupus, cancer
 - Hypersensitivity to vitamin D
 - Any contra-indication to having an MRI scan
 - Known severe kidney and cardiac problems
 - Malabsorption
 - Significant trauma to the knees including arthroscopy
 - knee or hip surgery in the next 2 years
3. Once you are included in the study, you will attend assessments at baseline, and then at 1 year and 2 years, with the option of three months and six months (maximum 6 visits including the screening visit). The study will go for two years as the effects of vitamin D on cartilage take this long to be measured adequately. The baseline and year 2 visits utilise a comprehensive protocol which takes about approximately 2.5 hours. Other visits will take about half an hour. Measures will be done at the Menzies Research Institute in Hobart for Tasmania participants and the Epworth Hospital and Caulfield Hospital in Melbourne for Victorian participants.
 4. The following measures will occur at visits as specified below:
 - a) Questionnaires that enquire about your joint symptoms, sunlight exposure, smoking, diet, depression, medications you have used and history of knee injury and surgery history at each visit.
 - b) Measurement of height, girth (hip and waist), body fat and blood pressure at baseline and final visits. Weight will be measured baseline and final visit.
 - c) Blood (up to 25 ml at the screening, 3 months and final visits) will be taken to look at serum vitamin D levels, calcium, phosphate, creatinine and other markers.
 - d) Knee X-ray at baseline.
 - e) Knee MRI (Magnetic Resonance Imaging) at baseline and final visits. The MRI scan will take about 20 minutes.
 - f) Measurement of physical activity using the International Physical Activity Questionnaire (IPAQ) short form and a pedometer at baseline and final visit. You will be asked to wear a pedometer for 7 days and to fill out a diary showing the times you were wearing it.
 - g) Measurement of muscle strength by dynamometry in the lower limb and hand at all visits.
 - h) Measurements of vital signs, adverse events, and pill counts will occur at all visits.
 5. Take either a vitamin D supplement (50,000 IU each tablet) or a placebo tablet each month. Placebo tablets do not contain any active ingredient. As this is a blinded trial you will be unaware of which type of tablets you have received until we have completed the study.

